K112300

JAN 19 2012

510(k) Summary for the Kimberly-Clark* Corporation KimGuard Smart-Fold* Sterilization Wrap (Models KC250, KC450, KC550 and KC650)

Device type:	Sterilization Wrap
Date of Summary:	July 28, 2011
510(k) Submitter:	Brenda Shelkey Associate Director, Quality Assurance & Regulatory Affairs KIMBERLY-CLARK CORPORATION 1400 Holcomb Bridge Road Roswell, GA 30076 678-654-8021 Brenda.Shelkey@kcc.com Establishment Registration Number 1033422
Primary Contact for this 510(k) Submission:	Same as above
Classification Regulation:	21 CFR 880.6850
Device Class:	Class II
Panel:	General Hospital
Product Code:	FRG

Intended Use:

KimGuard Smart-Fold* Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270°F/132°C for 4 minutes or by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/ 55°C and 40% - 80% relative humidity for 60 minutes. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened. The wrap was validated for aeration times for EO sterilization of 8 hours at 131°F/ 55°C or 12 hours at 110°F/ 43.3°C. The KimGuard Smart-Fold* Sterilization Wrap was validated for dry times for pre-vacuum steam sterilization of 20 minutes for Model KC250 and for dry times of 30 minutes for Models KC450, KC550 and KC650.

Wrap Model Recommendations for Pre-Vacuum Steam and for 100% Ethylene Oxide Sterilization[1]

KIMGUARD SMART-FOLD* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC250	Light Weight Package (for example: standard linen packs)	6 lbs.	2 huck towels (17 in. x 29 in.) 2 fluid-resistant U-drapes (68 in. x 109 in.) 1 fluid-resistant universal bar drape (70 in. x 108in.)
KC450	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 11 lbs. of metal mass
KC550	Heavyweight Package (for example: general use medical instruments)	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 15 lbs. of metal mass
KC650	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 23 lbs. of metal mass

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the KIMGUARD* and KIMGUARD ONE-STEP* Sterilization Wraps (i.e., the number and size of the fluid-resistant linens or the weight of the metal mass).

Device Description: KimGuard Smart-Fold* Sterilization Wrap is comprised primarily of two pieces of KimGuard Sterilization Wrap fabric (the blue base layer and the white intermediate layer). The fabric is a nonwoven spunbond-meltblown-spunbond (SMS) fabric composed of a top (inner) layer of spunbond, a center layer of meltblown, and a bottom (outer) layer of spunbond. SMS nonwoven fabrics are composed of polypropylene and white titanium dioxide and phthalocyanine blue pigments. Two strips of blue SMS are adhesively bonded to the white SMS intermediate layer for added strength. The reinforcement strips also contain a "reference line" feature designed to indicate proper sterilization tray placement to the user. Adhesive tape strips with release liners are included to secure the inner layers of the package. Users remove the release liners and use these adhesive strips to secure the wrap prior to sterilization. The Smart-Fold product also incorporates handles and pulls tabs comprised of blue SMS material and adhesive branding labels for aseptic opening.

Predicate Device: The KimGuard Smart-Fold* Sterilization Wrap (Models KC250, KC450, KC550, and KC650) is substantially equivalent to the predicate KimGuard One-Step* Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600) (K082177).

Substantial Equivalence: The modified design of KimGuard Smart-Fold* Sterilization Wrap is substantially equivalent to the predicate Kimberly-Clark KimGuard* One-Step* Sterilization Wrap (K082177) in intended use, design, and materials.

Summary of Testing: KimGuard Smart-Fold* Sterilization Wrap has been tested in compliance with the applicable requirements recommended in *Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA* (March 7, 2002). Testing included irritation and sensitization biocompatibility methods of ISO 10993 sterilant penetration, dry time, and physical integrity. The wrap has also been tested for the ability to maintain sterility of pack contents after sterilization for up to 30 days under standard conditions. All test results met acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 19 2012

Ms. Brenda Shelkey
Associate Director, Quality Assurance & Regulatory Affairs
Kimbery- Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Re: K112300
Trade/Device Name: KimGuard Smart-Fold* Sterilization Wrap (Models KC250, KC450, KC550, AND KC650)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 4, 2012
Received: January 5, 2012

Dear Ms. Shelkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

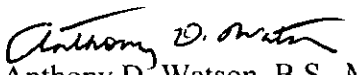
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K112300

Device Name: KimGuard Smart-Fold* Sterilization Wrap (Models KC250, KC450, KC550, and KC650)

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See Wrap Model Recommendations on Page 2.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Jamieu-Weller

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112300

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